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(54) Title: SELF-EXPANDING, ADAPTABLE CAVITY PLUG FOR USE IN IMPLANTATION OF ENDO-JOINT PROSTHESIS

(57) Abstract

The plug is designed for insertion in an opening formed in a medullated bone to act as a cement barrier. It comprises a polymeric material expandable in volume by uptake of water or temperature increase. The plug is capable of increasing its dimensions in the femoral cavity, adapting its shape to the geometry of the intramedullary canal and in consequence, closing the latter firmly. The self-adapting, expandable plug is produced from biocompatible expandable polymers.

SELF-EXPANDING, ADAPTABLE CAVITY PLUG FOR USE IN IMPLANTATION OF ENDO-JOINT PROSTHESIS

This invention relates to a plug for insertion in an opening formed in a medullated bone to act as a cement barrier. Such implantable devices which can be used for temporary or permanent closing of the medullary cavity of the femur or other long-bones during the replacement with cemented endo-jointprostheses, in particular the femoral component of a total hip prosthesis and are generally called intramedullary plugs or more specifically femoral cavity plugs (FCP).

Total hip replacement is the most performed major therapeutic intervention in orthopaedic surgery.

Two types of prostheses are used for the total hip replacement, i.e. cementless and/or cemented types. In the case of cementless prostheses, the fixation of the prosthesis to bone should result from the bony attachment/ingrowth to the stem of the prosthesis. In the case of cemented prostheses, a methylmethacrylate monomer (cement) is first injected into the reamed medullary cavity of the femur and subsequently the stem of the prosthesis is pressed in. Polymerization of the monomer should provide fixation of the prosthetic device to bone.

The drawback of this surgical procedure is related to the fact that upon injection of the cement, it flows freely down the medullary cavity. In consequence, there is no sufficient pressure generated which would allow for the uniform intrusion of the cement into the trabecular spaces of the surrounding bone of the trochanteric area as well as perfect filling of the created cavity, and thus adequately fix the prosthesis. This frequently results in weakening of the fixation.

To overcome this problem, femoral cavity plugs (FCP) of various shapes were proposed to close the intramedullary cavity and protect against downflow of the cement (pressure-injection techniques). Examples of such a plugs are described in detail in US-A-4 293 962, US-A-4 950 295 and US-A-4 344 190.

Existing FCP implants suffer, however, from the same drawbacks, i.e. they do not increase and/or increase only minimally their dimensions after insertion, do not properly adapt to the medullary cavity, and in consequence, they do not adequately close the medullary cavity of the femur.

Additional problems arise when the FCP implants have to be removed during the revision procedure, as they can hardly be found in the cavity.

To solve the problem of plug removal, the FCP implants were also produced from resorbable polymers such as polylactides, polyglycolide, polydioxanone, polyglycolide-co-trimethylene carbonate, etc. as described in US-A-4 950 295 and US-A-4 344 190.

But similarly to the existing nonresorbable FCP implants, the resorbable FCP they do not substantially swell/increase their dimensions in the tissue environment either, they do not adapt to the medullary cavity, and do not satisfactorily protect against the cement downflow. Moreover, the hollow, thin-wall cone-like structures utilized in some commercial designs of resorbable FCP, collapse easily upon insertion into the cavity which additionally reduces their functionality.

There exist also plugs which can expand its shape mechanically, e.g. as disclosed in US-A-4 276 659 or EP 58 744. These known plugs, however, collapse easily in the medullary cavity and never adapt to its contour. In consequence they do not close adequately the medullary cavity.

The present invention as claimed is intended to solve the drawbacks of existing polymeric femoral cavity plugs (FCP) used in the total hip replacement surgery with cemented prostheses by providing an intramedullary plug being made of polymeric material and being self-expanding and adapting its dimensions to the cross-section of the medullary cavity.

In accordance with the invention, this object is accomplished by the features of the characteristic part of claim 1.

The plug according to the invention is capable of increasing its dimensions in the femoral cavity, adapting its shape to the geometry of the intramedullary canal and in consequence, closing the latter firmly. The self-adapting, expandable FCP plugs of the invention are preferably produced from biocompatible polymers which, due to their chemical and/or physical characteristics are able to increase their dimensions.

The process of plug expansion can result from the substantial absorption of water from tissue fluids resulting in the swelling of the polymeric material.
This process can also be caused by the change in polymer structure from glassy to rubbery, which takes place when polymer is heated above the glass-transition temperature, e.g. from room to body temperature. The significant changes in elastic modulus that occur in the vicinity of the T_g lead to large dimensional changes.

Although the FCP of the invention can be produced from both the nonresorbable/nondegradable and/or resorbable/degradable/ soluble polymers, the resorbable/degradable/soluble polymers are preferred as their resorption, degradation, and/or dissolution in the femoral cavity solves the problem of plug removal during reoperation.

The expandable FCP of the invention are prepared from absorbent polymers which when in contact with an aqueous environment take up from 2 to 5000 weight-% of water as compared with their weight in the dry form, and preferably at least 5 weight-% of as related to their weight in the dry form.

Typical nonresorbable/nondegradable polymers to be used for the FCP of the invention are for example various polyacrylates such as polyhydroxymethyl methacrylate, polyhydroxyethyl meth-acrylate, and other superabsorbent acrylates, e.g. poly sodium acrylate. They can be used alone and/or in combination with various nonresorbable cellulose derivatives, e.g. hydroxyethyl, hydroxypropyl or cross-linked carboxymethylcellulose etc.

Another group of water absorbent polymers are hydrophilic polyurethanes, e.g. based on isophorone diisocyanate, 4,4'-dicyclohexamethylene diiosocyanate, trans-1,4-cyclohexane diisocyanate, di-meryl diisocyanate, 4,4'-diphenylmethane-diisocyanate with polyols, preferably polyethylene oxide, epoxies, acrylics or various other chain extenders.

Polymers of interest are so-called shape-memory thermoplastics e.g. polyurethane-based softenable shape-memory polymers, which can decrease and/or increase the dimensions when heated from room temperature to body temperature.

Typical absorbent resorbable/degradable/soluble polymers for the FCP plugs of the invention are various polysaccharides, e.g. cellulose derivatives produced by oxidation of various cellulose materials such as 2,3-dialdehyde cellulose or 6-carboxy cellulose.

Another polysaccharide of interest for the FCP is alginic acid a linear copolymer composed of two monomeric units, D-mannuronic acid and L-guluronic acid. Its calcium salt is bioresorbable, but not soluble in water, while the sodium salt is bioresorbable and water soluble. Mixing of these calcium and sodium alginates produces materials whose dissolution/ resorption rate can easily be controlled.

When degraded, the alginates break down to simple glucose-type residues and finally to carbon dioxide and water.

Alginate materials may take up to 200 weight-% of water in the loose form. Alginates in compressed form may take up to 600 weight-% of water as related to its weight in dry form. This in addition can be enhanced by applying special geometrical shapes to the final plugs. The latter may have the shape of a solid cone with fins on its surface or of a cylinder, preferably with regularly disposed indents on its surface or a shape of rosette.

Alginates are non-toxic and used in the food industry as additives to various products. They are also biocompatible and

seem to have a marked effect on the healing of wounds. Their medical applications include skin dressings to treat full-thickness skin wounds, haemostats and carriers for encapsulation of islet of Langerhans (the artificial pancreas). Alginate wool was used

- in the treatment of tooth sockets alone and loaded with antibiotics as described by J.F.S. Rumble, Twenty-five dental cases treated with absorbable alginate wool, British Dental Journal, April 14, 1949, 203;
- for haemostasis in neurosurgical practice as described by L.C.Oliver, G.Blaine, Haemostasis with absorbable alginates in neurosurgical practice, British Journal of Surgery 147, 307 (1950);
- for the treatment of tissue wounds when the alginate film/gel is formed in situ after injecting a solution of sodium alginate and calcium chloride into e.g. a muscle, as described by G.Blaine, Experimental observations on absorbable alginate products in surgery, Annals of Surgery, 125, 102 (1947) whereby the same concept of in situ transition of sodium alginate into calcium alginate has been the subject of US-A-5 266 326 (1993).

It has been found that the tissue reaction to alginates depends on the ratio of mannuronic to guluronic unit content. Therefore alginates with high guluronic content are preferred to be used for the plug of the invention as they do not interfere with the human immune system.

The absorbent/shape memory polymers mentioned are examples only and do not aim to exhaust the complete list of biocompatible polymers which can be used for the self-expanding FCP of the invention. The use of other absorbent/shape memory polymers for such applications will be obvious for anyone skilled-in-the-art.

The self-expanding FCP of the invention can be in the form of densely packed woven and nonwoven fibrous structures, compact solid elements, or a combination of fibrous and solid components. Preferably the FCP are in a compressed form adding to their expandability.

The FCP of the invention can have various geometrical shapes as described above and can be introduced in the medullar cavity using a tube-in-the-tube introducer as described in detail in the US-A-4 293 962.

Example I

Continuous monofilaments from calcium alginate were wound-up onto a PTFE mandrel with a diameter of 15 mm. The resulting structure was placed into the piston-cylinder device with a circular cross-section and subsequently compressed in the dry form at 60°C and 10 bar for 5 minutes. Next, pressure was released and the resulting plug was removed from the mould. The

plug was inserted into the thin-wall tube from medical grade stainless steel and next another tube with closed ends was introduced into the first tube to act as a piston for the release of the FCP.

The FCP-introducer system was inserted into the reamed medullary cavity of the cadaveric femur freshly rinsed with water. The marks on the wall of the external tube allowed for a controlled placing of the introducer at the required level in the medullary cavity. Next the internal tube was pressed downwards pushing out the plug into the cavity. Finally the introducer was withdrawn. An instant swelling of the plug led to a firm closing of the canal as it was checked by injection of a polymethylmethacrylate (PMMA) cement.

Example II

99 grams of calcium alginate powder was swollen in a solution containing 1 gram of sodium alginate in 50 ml of water and subsequently water was removed from the system by drying the material in a vacuum oven. Next the dry material was placed in the piston-cylinder device and pressurized at 20 bar and 70°C for 10 minutes. The resulting plug was placed in water which resulted in a 200% increase of the plug diameter.

Example III

20 gram of sodium alginate was dissolved in deionized water to produce 1% weight/volume solution. The solution was poured in the glass ampoule with circular cross-section and next 40 ml of 1 weight/volume-% solution of calcium chloride in deionized water was poured into the ampoule. The system was allowed for gelling due to sodium-calcium ion exchange. Next the excess of calcium chloride was removed and water present in the system was evacuated under vacuum. The resulting solid, void-free plug was removed from the ampoule and place in water which resulted in 100% increase of the plug diameter.

Example IV

The FCP was produced from oxidized cellulose using the technique described above. The cellulose material initially had the form of a loose staple fibres resembling cotton wool. The compressed FCP was placed in the tube-in-the-tube introducer from PEEK. The plug-introducer system was inserted into the medullary cavity of a transparent model of the human femur produced by the CAD stereolithography. The plug was released into the cavity and the introducer withdrawn. The inside of the cavity was moisturized with water which resulted in plug expansion and locking the intramedullary canal.

Example V

50 gram of carboxymethyl cellulose was dissolved in 200 ml of water to form a viscous solution. The solution was extruded through the spinneret into a preheated chamber connected to a two-stage rotary pump. Removal of water from the extruded solution resulted in a bundle of continuous monofilaments. these were compressed in a cylindrical mould into a FCP plug. When placed in water the plug diameter increased to about 60% of its initial diameter in a dry state.

Claims

1. Plug for insertion in an opening formed in a medullated bone to act as a cement barrier, characterized in that said plug comprises a polymeric material expandable in volume.

2. Plug according to claim 1, characterized in that said polymeric material is expandable in volume by uptake of water.

3. Plug according to claim 2, characterized in that said polymeric material, if placed in a aqueous environment, is able to absorb from 2 to 5000 weight-% of water as related to its weight in the dry state.

4. Plug according to claim 2, wherein said polymeric material is able to absorb at least 5 weight-% of water as related to its weight in the dry state.

5. Plug according to claim 2, wherein said cross-section is able to increase in a aqueous environment at least 5 % as compared with said cross-section in the dry state.

6. Plug according to claim 1, characterized in that said polymeric material is expandable in volume by temperature increase.

7. Plug according to claim 6, characterized in that said polymeric material is capable to increase its volume when heated from room temperature to body temperature.

8. Plug according to claim 6 or 7, characterized in that said polymeric material is chosen from the group of softenable, memory polymers which increase their dimension at body temperature, preferably polyurethane-based materials.

9. Plug according to one of the claims 1 - 8, characterized in that said polymeric material is resorbable.

10. Plug according to one of the claims 1 - 8, characterized in that said polymeric material is degradable.

11. Plug according to one of the claims 1 - 8, characterized in that said polymeric material is soluble in aqueous solutions.

12. Plug according to one of the claims 1 - 8, characterized in that said polymeric material is nondegradable.

13. Plug according to one of the claims 1 - 12, characterized in that said plug has essentially no hollow geometrical structure.

14. Plug according to one of the claims 1 - 13, characterized in that said plug has the shape of a solid cone, preferably with fins on its surface.

15. Plug according to one of the claims 1 - 13, characterized in that said plug has the shape of a cylinder, preferably with regularly disposed indents on its surface and/or a rosette-like geometry.

16. Plug according to one of the claims 1 - 15, characterized in that said plug comprises fibrous polymeric material.

17. Plug according to one of the claims 1 - 16, characterized in that said plug comprises continuous fibres.

18. Plug according to one of the claims 1 - 16, characterized in that said plug comprises staple fibres.

19. Plug according to one of the claims 1 - 18, characterized in that said plug is made of a solid, void-free block.

20. Plug according to one of the claims 1 - 19, characterized in that said polymeric material is present in a compressed form.

21. Plug according to one of the claims 1 - 20, characterized in that said polymeric material is chosen from the group of alginates, preferably from the group of calcium alginates.

22. Plug according to claim 21, characterized in that said alginates have a high guluronic content, preferably more than 50 weight-%.

23. Plug according to one of the claims 1 - 20, characterized in that said polymeric material is carboxymethyl cellulose.

24. Plug according to one of the claims 1 - 23, characterized in that said plug has a density of between 0.6 to 3.0 g/cm^3, preferably of between 0.8 to 2.0 g/cm^3.

25. Plug according to one of the claims 1 - 20, characterized in that said polymeric material is chosen from the group of polyacrylates, preferably from polyhydroxymethyl methacrylate, polyhydroxyethyl methacrylate, and polysodium acrylate.

26. Plug according to one of the claims 1 - 20, characterized in that said polymeric material is chosen from the group of hydrophilic polyurethanes, preferably based on isophorone diisocyanate, 4,4'-dicyclohexamethylene diiosocyanate, trans-1,4-cyclohexane diisocyanate, di-meryl diisocyanate, 4,4'-diphenylmethane diisocyanate with polyols, preferably polyethylene oxide, epoxies or acrylics as chain extenders.

27. Plug according to one of the claims 1 - 20, characterized in that said polymeric material is chosen from the group of polysaccharides, preferably from cellulose derivatives produced by oxidation of cellulose materials.

28. Plug according to one of the claims 1 - 20, characterized in that said polymeric material is chosen from the group of anionic and neutral microbial polysaccharides, preferably xanthan gum or gellan gum.

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/IB 95/00386

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61L27/00 A61F2/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61L A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	FR,A,2 616 319 (SCIENCE ET MEDECINE) 16 December 1988 see claims 1,3,5 ---	1,21
A	FR,A,2 570 606 (LABORATOIRE LANDANGER) 28 March 1986 see page 2, line 1 - line 2 see page 3, line 14 - line 15; claims 1,3 ---	1,2,9,11
A	EP,A,0 023 787 (UNIVERSITY OF EXETER) 11 February 1981 see claim 3 ---	9-11
A	FR,A,2 683 992 (BOUCHER G.) 28 May 1993 ---	

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
11 September 1995	06.10.95
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP,A,0 338 981 (ROBERT MATHYS CO) 25 October 1989	

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
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